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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,632	12/08/2003	Chau-Ting Yeh	14176-003001	9429

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EXAMINER	
MONTANARI, DAVID A	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,632	YEH, CHAU-TING	
	Examiner	Art Unit	
	David Montanari	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/04/2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-28 are pending in the instant application.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, and 14, drawn to an isolated nucleic acid sequence comprising a nucleotide sequence at least 70%, 80%, 90%, 95%, 100% identical to SEQ ID NO: 1, a cell comprising said nucleotide sequence, an isolated nucleic acid that hybridizes under stringent conditions to SEQ ID NO: 1, or a complementary sequence thereof, and a method of expressing said isolated nucleic acid that hybridizes to SEQ ID NO: 1 in a cell , classified in class 536, subclass 23.1.

II. Claims 7-11, drawn to a pure polypeptide comprising an amino acid sequence encoded by a nucleic acid comprising a nucleotide sequence that is at least 70%, 80%, 90%, 95% identical to SEQ ID NO: 1, a polypeptide wherein the amino acid sequence is SEQ ID NO: 2, classified in class 530, subclass 300.

III. Claims 13, drawn to an antibody against a polypeptide encoded by SEQ ID NO: 2, classified in class 530, subclass 387.1.

IV. Claims 17-18, drawn to a method of determining whether a subject is suffering from or at risk for developing an abnormal liver condition, an adenocarcinoma, or a combination thereof, classified in class 435, subclass 6.

V. Claims 19-20, drawn to a method of identifying a compound for treating an abnormal liver condition, an adenocarcinoma, or a combination thereof, classified in class 435, subclass 29.

VI. Claims 21-24, and 27, drawn to a method of treating an abnormal liver condition, an adenocarcinoma, or a combination thereof, comprising administering an effective amount of a compositions to decrease a level of nucleic acid encoded by SEQ ID NO: 1 or a polypeptide encoded by SEQ ID NO: 2, wherein the composition includes a nucleic acid encoding a transcript that hybridizes under stringent conditions to SEQ ID NO: 1, classified in class 514, subclass 44.

VII. Claims 21-22, 25-26, and 28, drawn to a method of treating an abnormal liver condition, an adenocarcinoma, or a combination thereof, comprising administering an effective amount of a compositions to decrease a level of nucleic acid encoded by SEQ ID NO: 1 or a polypeptide encoded by SEQ ID NO: 2, wherein the composition is an antibody against the polypeptide of SEQ ID NO: 2, classified in class 424, subclass 134.1.

Groups I and II are distinct. Group I is drawn to an isolated nucleic acid sequence and a cell comprising said sequence, an isolated nucleic acid that hybridizes to SEQ ID NO:1, and a method of expression said isolated nucleic acid in a cell. Group II is drawn to a pure polypeptide comprising an amino acid sequence encoded by SEQ ID NO:1, and a polypeptide encoded by SEQ ID NO:2. The nucleic acid of Group I has materially different and separate uses than the polypeptide of Group II.

Groups I and III are distinct. Group I is drawn to an isolated nucleic acid sequence and a cell comprising said sequence, an isolated nucleic acid that hybridizes to SEQ ID NO:1, and a method of expression said isolated nucleic acid in a cell. Group III is drawn to an antibody against a polypeptide encoded by SEQ ID NO:2. The nucleic acid of group I can be used in gene therapy, the antibody of Group III can be used in assays such as binding and immunohistochemistry which requires materially different and separate protocols from Group I.

Groups I and IV are distinct. Group I is drawn to an isolated nucleic acid sequence and a cell comprising said sequence, an isolated nucleic acid that hybridizes to SEQ ID NO:1, and a method of expression said isolated nucleic acid in a cell. Group IV is a method of assay by determining the presence of a nucleic acid or polypeptide. The nucleic acid of Group I is not required for the assay of Group IV.

Groups I and V are distinct. Group I is drawn to an isolated nucleic acid sequence and a cell comprising said sequence, an isolated nucleic acid that hybridizes to SEQ ID NO:1, and a method of expression said isolated nucleic acid in a cell. Group V is a method of assay by determining whether a compound lowers the levels of a nucleic acid or polypeptide in a cell. The nucleic acid of Group I is not required for the assay of Group V.

Groups I and VI are distinct. Group I is drawn to an isolated nucleic acid sequence and a cell comprising said sequence, an isolated nucleic acid that hybridizes to SEQ ID NO:1, and a method of expression said isolated nucleic acid in a cell. Group VI is method of treatment with a nucleic acid that hybridizes under stringent conditions to SEQ ID NO: 1. The nucleic acid of Group I can be used as gene therapy, the nucleic acid

of Group VI can be used in antisense therapy which requires materially different and separate protocols for treatment.

Groups I and VII are distinct. Group I is drawn to an isolated nucleic acid sequence and a cell comprising said sequence, an isolated nucleic acid that hybridizes to SEQ ID NO:1, and a method of expression said isolated nucleic acid in a cell. Group VII is a method of treatment with an antibody. The nucleic acid of Group I can be used as gene therapy, the method of treatment with the antibody of Group VII requires materially different and separate protocols for treatment.

Groups II and III are distinct. Group II is drawn to a pure polypeptide comprising an amino acid sequence encoded by SEQ ID NO:1, and a polypeptide encoded by SEQ ID NO:2. Group III is drawn to an antibody against a polypeptide encoded by SEQ ID NO:2. The antibody of Group III can be used in methods of treatment which require materially different and separate protocols, and does not require the polypeptide of Group II for treatment.

Groups II and IV are distinct. Group II is drawn to a pure polypeptide comprising an amino acid sequence encoded by SEQ ID NO:1, and a polypeptide encoded by SEQ ID NO:2. Group IV is a method of assay by determining the presence of a nucleic acid or polypeptide. The method of assay of Group IV does not require the polypeptide of Group II, which can be used in other assays such as binding assays.

Groups II and V are distinct. Group II is drawn to a pure polypeptide comprising an amino acid sequence encoded by SEQ ID NO:1, and a polypeptide encoded by SEQ ID NO:2. Group V is a method of assay by determining whether a compound lowers the

levels of a nucleic acid or polypeptide in a cell. The polypeptide of Group II is not required for the method of assay of Group V, and can be used for separate uses.

Groups II and VI are distinct. Group II is drawn to a pure polypeptide comprising an amino acid sequence encoded by SEQ ID NO:1, and a polypeptide encoded by SEQ ID NO:2. Group VI is method of treatment with a nucleic acid that hybridizes under stringent conditions to SEQ ID NO: 1. The polypeptide of Group II is not required for the method of treatment of Group VI, and can be used for separate uses.

Groups II and VII are distinct. Group II is drawn to a pure polypeptide comprising an amino acid sequence encoded by SEQ ID NO:1, and a polypeptide encoded by SEQ ID NO:2. Group VII is a method of treatment with an antibody. The polypeptide of Group II is not required for the method of treatment of Group VII, and can be of separate uses.

Groups III and IV are distinct. Group III is drawn to an antibody against a polypeptide encoded by SEQ ID NO:2. Group IV is a method of assay by determining the presence of a nucleic acid or polypeptide. The antibody of Group III can be used in assays such as immunohistochemistry, and is not required by the method of Group IV.

Groups III and V are distinct. Group III is drawn to an antibody against a polypeptide encoded by SEQ ID NO:2. Group V is a method of assay by determining whether a compound lowers the levels of a nucleic acid or polypeptide in a cell. The antibody of Group III can be used in assays such as immunohistochemistry, and is not required by the method of Group V.

Groups III and VI are distinct. Group III is drawn to an antibody against a polypeptide encoded by SEQ ID NO:2. Group VI is method of treatment with a nucleic

acid that hybridizes under stringent conditions to SEQ ID NO: 1. The antibody of Group III is not required for the method of treatment of Group VI.

Groups III and VII are distinct. Group III is drawn to an antibody against a polypeptide encoded by SEQ ID NO:2. Group VII is a method of treatment with an antibody. The antibody of Group III can be used in *in vitro* assays, which require materially different and separate protocols from the *in vivo* treatment of Group VII.

Groups IV and V are distinct. Group IV is a method of assay by determining the presence of a nucleic acid or polypeptide. Group V is a method of assay by determining whether a compound lowers the levels of a nucleic acid or polypeptide in a cell. The method of Group V requires materially different and separate protocols from Group IV.

Groups IV and VI are distinct. Group IV is a method of assay by determining the presence of a nucleic acid or polypeptide. Group VI is method of treatment with a nucleic acid that hybridizes under stringent conditions to SEQ ID NO: 1. The method of assay of Group IV does not require treatment, the method of treatment of Group VI requires materially different and separate protocols from that of Group IV.

Groups IV and VII are distinct. Group IV is a method of assay by determining the presence of a nucleic acid or polypeptide. Group VII is a method of treatment with an antibody. The method of assay of Group IV does not require treatment, the method of treatment of Group VII requires materially different and separate protocols from that of Group IV.

Groups V and VI are distinct. Group V is a method of assay by determining whether a compound lowers the levels of a nucleic acid or polypeptide in a cell. Group VI is method of treatment with a nucleic acid that hybridizes under stringent conditions to

SEQ ID NO: 1. The method of assay of Group V does not require treatment, the method of treatment of Group VI requires materially different and separate protocols from that of Group V.

Groups V and VII are distinct. Group V is a method of assay by determining whether a compound lowers the levels of a nucleic acid or polypeptide in a cell. Group VII is a method of treatment with an antibody. The method of assay of Group V does not require treatment, the method of treatment of Group VII requires materially different and separate protocols from that of Group V.

Groups VI and VII are distinct. Group VI is method of treatment with a nucleic acid that hybridizes under stringent conditions to SEQ ID NO: 1. Group VII is a method of treatment with an antibody. Groups VI and VII are methods of treatment which use different compounds for treatment. The nucleic acid of Group VI would require materially different and separate protocols of treatment from the antibody of Group VII.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143)

4. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and

process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required is different among each group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For

instructions, Applicants are referred to

http://www.uspto.gov/web/omces/dcom/olia/aipa/index.htm.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 1-571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 1-571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER